K041407

DEC 2 9 2004

510(k) SUMMARY

SUBMITTED BY

Wendy Spielberger, RAC
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Interpore Cross International
181 Technology Drive
Irvine, California 92618
(949) 453-3200

Date Prepared: May 26, 2004

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Spinal Intervertebral Fixation Orthosis
Common/Usual Name:	Vertebral Body Replacement
Product Classification:	Class II
Product Code:	MQP
Proprietary Name:	Titanium Mesh Implant

PREDICATE DEVICE

DePuy Acromed Surgical Titanium Mesh (K003043 and K020522)

INTENDED USE

The Titanium Mesh Implant is indicated for use in the thoracolumbar spine (T1 to L5) for total replacement of diseased vertebral body(ies) resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Titanium Mesh Implant is also indicated for total vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The Titanium Mesh Implant is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The Titanium Mesh Implant is intended to be used with supplemental internal fixation. The supplemental fixation system that must be used with this implant is the Synergy Spinal System. In addition, the Titanium Mesh Implant is intended for use with bone graft.

DEVICE DESCRIPTION

The Titanium Mesh Implant is a hollow cylindrical tube made from commercially pure (CP) titanium (ASTM F-67). The sides of the cylinder implants contain concentric oval patterned openings. These openings allow the surgeon to trim the cylinder to the desired length at a pre-specified angle relative to the longitudinal axis of the cylinder. The external surface of the implant contains concentric circular grooves perpendicular to the axis of the cylinder which provides a guide in the event that a perpendicular end is desired.

COMPARISON TO THE PREDICATE DEVICE

Based on the same indications for use, intended use, similarity in materials of construction and equivalent biomechanical performance, the Titanium Mesh Implant is considered substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 2004

Ms. Wendy Spielberger
Lead Regulatory and Clinical Affairs Staff
Interpore Cross International
181 Technology Drive
Irvine, California 92618-2402

Re: K041407
Trade/Device Name: Titanium Mesh Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 15, 2004
Received: December 16, 2004

Dear Ms. Spielberger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as se forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Titanium Mesh Implant

Indications-For-Use:

The Titanium Mesh Implant is indicated for use in the thoracolumbar spine (i.e., T1 to L5) for total replacement of diseased vertebral body(ies) resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Titanium Mesh Implant is also indicated for total vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The Titanium Mesh Implant is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

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Prescription Use X **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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